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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Baker Donelson Bearman, Caldwell & Berkowitz, PC 555 Eleventh Street, NW, Sixth Floor Washington, DC 20004				
EXAMINER				
YU, MELANIE J				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/535,666

Applicant(s)

CORBETT ET AL.

Examiner

MELANIE YU

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) 1-15, 21, 22 and 25 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 16-20, 23, 24, 26 and 27 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 19 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 4 September 2009 has been entered.

Status of the Claims

2. Claims 1-27 are currently pending in this application. Claims 1-15, 21, 22 and 25 have been withdrawn and claims 16-20, 23, 24, 26 and 27 are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 16-18, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Werner et al. (US 2002/0168652).

Werner et al. teach a method of measuring the binding of a first partner in an interaction to a second partner in an interaction, wherein the interaction partners are molecular entities, the method comprising the steps of:

delivering a quantity of the second interaction partner to a reaction well of a device (disc has flow channels, which are reaction wells, par. 13) for attachment of the second interaction partner to an attachment zone of the reaction well (DNA capture probes are bound to the surface of the disc and are therefore delivered to the reaction

well, par. 13; capture DNA attached to a layer in the target zone, par. 55), wherein the device comprises:

an opaque temperature controlled chamber having a centrifuge rotor therein (chamber 112 is an optical disc drive and therefore opaque, par. 97, Fig. 1; disc is inside optical disc drive and is temperature controlled, therefore chamber is temperature controlled, par. 160; bio disc drive rotates the disc and therefore has a rotor, par. 9 and rotor can perform centrifugation, par. 13), the rotor having at or near the periphery of the rotor and attached thereto at least one radially positioned (radial fluidic circuit, par. 188; reaction wells are positioned radially near the center of the disc and therefore near the rotor, well 128 near center of disc where rotor is located, Fig. 2C) transparent reaction well (par. 105),

the reaction well having on an upper surface thereof an aperture for the addition of reagents to the reaction well (inlet port, 122, in cap portion which is an upper surface, 116, par. 100, Fig. 2C),

the reaction well further including on an internal surface thereof having at least one attachment zone for the second interaction partner (capture zone 140 is in internal surface of the reaction well 130 and is the attachment zone, par. 104, Fig. 2A),

the well having a sufficient length to provide an area for at least one attachment zone (well contains an attachment zone 140 and therefore has sufficient length to provide an area for the attachment zone, par. 104, Fig. 2A) and

an area positioned at the end of the well into which the solutions which are applied to the second interaction partner can be displaced by centrifugal force (solutions are displaced by removing unbound components by centrifugal force, par. 13-14; return channel, 132, is connected to the end of the flow channel well, 130, and is where solutions are displaced upon centrifugation, par. 8 and 109);

a system for detecting light emitted by an indicator molecule (par. 44 and 46); and

a means for controlling the temperature of the chamber and the operation of the rotor (par. 160);

adding a solution comprising a quantity of the first interaction partner to the attachment zone (test sample is injected into the flow channel, and contacted with the capture DNA, par. 84) and incubating at a temperature for a time sufficient to allowing binding of the first interaction partner to the second interaction partner (par. 137);

rotating the device rotor at a speed sufficient to displace the solution comprising unbound first interaction partner from the attachment zone (after hybridization, disc is rotated to clear the target zones of unattached sample and labels, par. 84); and

measuring the amount of the first interaction partner bound to the second interaction partner via fluorescence of an indicator molecule bound thereto (par. 62).

Although Werner et al. do not specifically teach the attachment zone being at the end of the well closest the axis of the rotor, the attachment zone taught by Werner et al., 140, Fig. 2B is contains portions that are at the inner most portion of the well (attachment zone, 140, closest to inlet, 122, Fig. 2B). The inner most portion of the well

of Werner et al. is closest to the center (inner circle) of the disc shown in Fig. 2B, which is where the rotor from the optical disc drive is placed. Therefore Werner et al. contains attachment zones in the portion of the well that is at the end of the well closest the axis of the rotor.

With respect to claim 17, Werner et al. teach the first and second interaction partners being a nucleic acid and a nucleic acid (analytes are DNA and capture molecules are DNA, par. 50 and 53).

Regarding claim 18, Werner et al. teach the first interaction partner delivered as a solution containing a buffer (par. 117) and the second interaction partner delivered as a solution containing a hybridization buffer (par. 125).

With respect to claim 20, Werner et al. teach carrying out the displacement step at a speed of 2000 rpm and 5000 rpm (par. 140), which is encompassed by the recited greater than 500 rpm.

Regarding claim 23, Werner et al. teach the indicator molecule being a cyanine dye, which is an intercalating dye (par. 62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652).

Werner et al. teach carrying out the step of adding a solution comprising a quantity of the first interaction partner with the rotor rotating (par. 83), but do not teach the specific rpm of the rotating rotor. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claims 19 are for any particular purpose or solve any stated problem, and the prior art teaches that the rpm may be varied to assist with mixing (par. 83). Absent unexpected results, it would have been obvious for one of ordinary skill to discover the

optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the biotechnology art.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652), as applied to claims 16 and 23, in view of Gjerde et al. (US 6,210,885).

Werner et al. teach the indicator molecule being an intercalating dye of cyanine, but fail to teach the dye being Sybr green.

Gjerde et al. teach a DNA binding dye of either cyanine or Sybr green (col. 8, line 53-col. 9, line 8), in order to provide detection of a DNA complex that is reversibly labeled.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include as the dye of Werner et al., Sybr green as taught by Gjerde et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected signal would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Gordon et al. (US 2002/0098528).

Werner et al. teach measuring fluorescence, but fail to teach the measuring step while the rotor is rotating at a speed of at least 500 rpm.

Gordon et al. teach moving an incident beam for detection in a detection chamber by rotating a biodisc about an axis (par. 19), in order to provide perpendicular scanning of the detection chamber.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al., rotating the biodisc as taught by Gordon et al., in order to provide fast detection of bound analyte.

Although Werner et al. in view of Gordon et al. do not specifically teach the rotating speed being at least 500 rpm. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation” Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). “No invention is involved in discovering optimum ranges of a process by routine experimentation.” Id. at 458, 105 USPQ at 236-237. The “discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.” Since applicant has not disclosed that the specific limitations recited in instant claim 26 are for any particular purpose or solve any stated problem, and the prior art teaches that the rotating speed may be varied in order to control the speed of detection. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the biodisc art.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Werner et al. (US 2002/0168652) in view of Almogy (US 6,236,454).

Werner et al. teach at least one reaction well having multiple attachment zones and measurement of the amount of the interaction partner bound to the second interaction partner via the fluorescence of an indicator molecule (148, Fig. 3; par. 12 and 67), but fail to teach detection using multiple detectors.

Almogy teaches detection of fluorescence in multiple regions (spots) using multiple photodetectors (multiple spots and one photodetector per spot, col. 2, line 56-col. 3, line 5), in order to resolve sufficiently small pixels by having the ability to place detectors at non-oblique angles.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Werner et al., multiple photodetectors with one photodetector per detection region as taught by Almogy, in order to increase the detection rate of a detection system.

Response to Arguments

8. Previous objections to the claim have been withdrawn in light of applicant's amendments.

9. Applicant's arguments filed 4 September 2009 have been fully considered but they are not persuasive. Applicant argues that the target or capture zones of Werner et al. cannot be directly equated to the attachment zone of the present invention. Applicant argues that the target or capture zone taught by Werner et al. is defined by the pre-existing fixation within this zone of a probe which is specific for a target

sequence to be detected, and the attachment zone of the instant claims is simply the region to which each of the interaction partners is added. Applicant argues that therefore the process of carrying out an assay to detect binding between two molecules is fundamentally different in Werner et al. in comparison to the present invention.

Applicant's argument is not persuasive because the claim does not reflect these differences. Rejected claim 16 uses open claim language "comprising" and therefore does not exclude the presence of addition elements such as the pre-existing fixation of probe molecules that are specific for a target sequence in the attachment area. Therefore the presence of immobilized capture probes in the attachment area of Werner et al. reads on the attachment area claimed in rejected claim 16.

10. Applicant further argues that Werner et al. neither teaches nor contemplates a device comprising 1) a rotor having at or near the periphery of the rotor and attached thereto at least one radially positioned transparent reaction well that includes an internal surface at the end closest the axis of the rotor at least one attachment zone for the second interaction partner, 2) the reaction well having a sufficient length to provide an area for the attachment zone and 3) an area positioned at the end of the well into which the solutions applied to the interaction partner can be displaced by centrifugal force.

Applicant's arguments are not persuasive and the elements that applicant's argue are not taught by Werner et al. are detailed in the rejection above with specific paragraph numbers. Further clarification with respect to each argued element is provided herein below.

1) With respect to the transparent reaction well that includes an internal surface having an attachment zone at the periphery of the rotor, at Figure 3A of Werner et al., the rotor is at the circular center of the disc when the disc is placed in the optical disc drive as described at paragraph 9 (rotor for rotating the bio-disc) and the reaction wells, 130, clearly radially extend from the center circle of the disc and therefore extend from the periphery of the rotor of the device. The cap portion of the reaction well is transparent, which provides a reaction well that is transparent, as described at paragraph 112, and the reaction well comprises the attachment zones, which are the target or capture zones, 140, taught at paragraph 13 and 110.

2) With respect to the reaction well having sufficient length to provide an area for the attachment zone, the reaction well taught by Werner et al. comprises the attachment zones, 140, as shown in Figure 2B, and therefore has sufficient length to provide an area for the attachment zone.

3) With respect to an area positioned at the end of the well into which the solutions are applied to the interaction partner can be displaced by centrifugal force, Werner et al. teach the solutions applied to the attachment area displaced by centrifugal force at paragraph 13 and 14. Werner et al. also teach an area at the end of the well, flow channel is well, reference number 130, and return channel is the area at the end of the well, reference number 132, Figure 2A. The return channel of Werner et al. is positioned connected to the "end" of the flow channel as shown in Figure 2A and Werner et al. teach solutions centrifuged from the attachment area. Therefore the

solutions applied to the second interaction partner of Werner et al. are capable of being displaced by centrifugal force.

Conclusion

11. No claims are allowed.
12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE YU** whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/
Primary Examiner, Art Unit 1641